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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,130	02/05/2002	Olga Bandman	PF-0319-2 DIV	2603

7590 11/05/2002

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EXAMINER
STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/05/2002 3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,130	BANDMAN ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,12 and 29-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,11,12 and 29-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

Claims 1, 11, 12, and 29-45 are pending in the application.

Preliminary amendment to cancel claims 2-10, 13-28, and 46-57 in Paper No. 2 is acknowledged.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim(s) 1, drawn to an isolated polypeptide, classified in class 435, subclass 196.

II. Claim(s) 11, 31, 32, 34, and 36-43, drawn to an isolated antibody that binds to a polypeptide, a composition thereof, a method of preparing a polyclonal antibody, a polyclonal antibody, a composition thereof, a method of making a monoclonal antibody, a monoclonal antibody, and a composition thereof, classified in class 530, subclass 387.9.

III. Claim(s) 12, drawn to an isolated polynucleotide, classified in class 536, subclass 23.2.

IV. Claim(s) 29, drawn to a method of assessing the toxicity of a test compound, classified in class 435, subclass 6.

V. Claim(s) 30, 33, and 35, drawn to a diagnostic test for a condition or disease associated with the expression of PROPHO or a method for diagnosing a condition or disease associated with the expression of PROPHO, classified in class 435, subclass 7.4.

VI. Claim(s) 44, drawn to a method of detecting a polypeptide, classified in class 435, subclass 7.4.

VII. Claim(s) 45, drawn to a method of purifying a polypeptide, classified in class 435, subclass 196.

2. The inventions are distinct, each from the other because:

3. The polypeptide of Group I, the antibody of Group II, and the polynucleotide of Group III each comprises a chemically unrelated structure capable of separate manufacture, use, and effect. The polynucleotide of Group III has other utility besides encoding polypeptides such as a hybridization probe,

the polypeptides of Group I can be made by another method such as purification from the natural source or *in vitro* synthesis, and the antibody of Group II can be made by a protein other than the protein of Group I such as a protein purified from the natural source or a protein synthesized *in vitro*.

4. The polypeptide of Group I is unrelated to the method(s) of Group IV as it is neither used nor made by the method(s) of Group IV.

5. The polypeptide of Group I and the methods of Groups V-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I can be used as antigen in the production of antibodies.

6. The antibody of Group II is unrelated to the method(s) of Group IV as it is neither used nor made by the method(s) of Group IV.

7. The antibody of Group II and the methods of Groups V-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group II can be used for methods other than diagnosing a condition or disease (Group V) or detecting a polypeptide (Group VI) such as for purification of a polypeptide and the antibody of Group II can be used for a method other than purifying a polypeptide (Group VII) such as for diagnosing a condition or disease.

8. The polynucleotide of Group III and the method of Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the polynucleotide of Group III can be used for expression of a polypeptide.

9. The polynucleotide of Group III is unrelated to the method(s) of Groups V-VII as it is neither used nor made by the method(s) of Groups V-VII.

10. The methods of Groups IV-VII are independent as they comprise different steps, utilize different products and yield different results.

11. MPEP 803 sets forth two criteria for restricting between patentably distinct inventions – 1) the inventions must be independent or distinct and 2) there must be a serious burden on the examiner. MPEP 803 states, "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02". The first criterion for restriction has been satisfied as the inventions of Groups I-VII are independent or distinct for the reasons given above. Inventions I-VII have separate classification and/or each invention requires a separate patent and non-patent literature and/or sequence search. Because each of the inventions listed as Groups I-VII text and/or sequence search, the second criterion for restriction has been satisfied.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600